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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/685,058 | 10/14/2003 | Wallace J. Gardner | 632P002 | 5709 |
| 42754 | 7590 | 11/02/2006 | EXAMINER | |
| NIELDS & LEMACK 176 EAST MAIN STREET, SUITE 7 WESTBORO, MA 01581 | | | KIM, JENNIFER M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/685,058 | GARDNER, WALLACE J. | |
| | Examiner | Art Unit | |
| | Jennifer Kim | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 August 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 13 and 14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 7-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/2/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group II, Claims 7-12, drawn to a method of reducing plaque formation on teeth of a mammal, comprising brushing said teeth a composition comprising a plaque formation inhibiting effective amount of a tetracycline in a liquid vehicle, classified in class 514, subclass 152 is acknowledged. Accordingly, claims 1-6 are withdrawn from consideration because they are non-elected invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being **enabling for the “effective amount”** for reducing plaque formation, **does not reasonably provide enablement for the “inhibiting effective amount”**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).

These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of reducing plaque formation or tooth decay on teeth of a mammal, comprising brushing said teeth a composition comprising a plaque formation **inhibiting** effective amount of a tetracycline in a liquid vehicle. The nature of the invention is extremely complex in that it encompasses the actual **inhibition amount** of plaque formation in vivo such that the subject treated with the certain amount of tetracycline does not develop plaque formation.

Breadth of the Claims: The complex of nature of the claims greatly exacerbated by breadth of the claims. The claims encompass **inhibition equating to an absolute prevention** of plaque formation in humans which has potentially many different causes (i.e. many different mutations or combination of mutations, bacterial infection, medical condition/disorders, medication regimen). Each of which may or may not be addressed by the administration of the claimed “**inhibiting effective amount**” of tetracycline.

Guidance of the Specification: The guidance given by the specification as to how one would determine the claimed amount of tetracycline to a subject in order

to actually **inhibit/prevent (absolute) plaque formation in vivo** is minimal. All of the guidance provided by the specification is directed towards **the effective amount of tetracycline to reduce plaque formation** rather than **inhibiting effective amount equating to preventing amount**.

Working Examples: All of the working examples provided by the specification are directed toward the **effective amount to reduce plaque formation** rather than **inhibiting effective amount**.

State of the Art: While the state of the art is relatively high with regard to effective amount to reduce plaque formation (i.e. **effective amount to treat or reduce gingivitis**), the state of the art with regard to the amount that **inhibit/prevent** of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein an effective amount of compound similar to the claimed compounds was administered to a subject to **inhibit/prevent** development of plaque formation. The state of art, Gaffar et al. (U.S. Patent No. 5,605,676) report that it is **difficult** to maintained an **effective level** of the antibacterial agents responsible for **plaque formation** on dental tissue for a significant time period after their application. (column 1, lines 30-35).

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the **actual amount that inhibit/prevent plaque formation** in a human subject with the claimed compounds makes practicing the

claimed invention unpredictable in terms of the amount **that inhibits formation of plaque.**

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed **inhibiting amount** and test the **inhibiting amount** in the model system to determine whether or not the amount is effective for **absolute inhibition/prevention of plaque formation.** If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard the amount that inhibit/prevent (absolute) plaque formation with any amount, one of skill in the art would have to then either envision a modification of the first amount of pharmaceutical compound, compound effective dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new amount of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding amount that provide **absolute inhibition/prevention of plaque formation of any amount,** the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to reduce plaque formation on teeth of a mammal, comprising brushing

said teeth a composition comprising a plaque formation **inhibiting effective amount** of a tetracycline in a liquid vehicle.

Therefore, a method of reducing plaque formation on teeth of a mammal, comprising brushing said teeth a composition comprising a plaque formation or tooth decay **inhibiting effective amount** of a tetracycline in a liquid vehicle is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNamara et al. (U.S. Patent No. 5,223,248).

McNamara et al. teach a method of inhibiting **plaque formation on mammalian tooth surface comprising tetracycline** in various **oral hygiene products** such as dentifrices, lozenges, chewing gums, **mouth wash (liquid)** and the like to contract the tooth surfaces and prevent **plaque accumulation** thereon. (abstract). McNamara et al. illustrates dentifrice composition comprising **water**. (Examples, particularly example VII). McNamara et al. teach that tetracycline can be included in toothpaste, normal **brushing** one to three times daily. (column 5, lines 5-10). McNamara et al. teach that by preventing plaque formation on tooth surfaces removes a critical step in the pathologic process of **tooth decay**. (column 3, lines 34-45). McNamara et al. teach the preparation can be ranging from about 10mg% to about 100mg% of tetracycline. (column 3, lines 15-20). McNamara et al. report that plaque formation ultimately leads to **root caries**, a leading cause of tooth loss in adults. (column 1, lines 25-31).

McNamara et al. do not illustrate example of brushing teeth of a mammal for reducing plaque formation comprising liquid tetracycline and the specific mammal population, human.

It would have been obvious to one of ordinary skill in the art to employ the oral hygiene product comprising tetracycline to human subject for inhibiting plaque formation because McNamara et al. teach that dental product comprising tetracycline is effective for preventing plaque accumulation and because normal brushing with the composition three times a day is effectively performed. It is noted that plaque control can be achieved by mechanical mean of brushing alone. One would have been motivated to employ the oral dental hygiene product comprising tetracycline taught by McNamara et

al. combined with brushing in order to avoid root caries which is a leading cause of tooth loss in adult human.

Claims 7-12 are rejected under 35 U.S.C..103(a) as being unpatentable over Wu et al. (WO 2004/093876A2).

Wu et al. teach composition for controlling oral pathogens in **mammals** including **humans** comprising tetracyclines including **doxycycline**. (abstract, page 5, lines 4-10). Wu et al. teach that **dental plaque** frequently is associated with oral diseases, including **dental caries** and that plaque control can be achieved by mechanical (e.g. **brushing** and flossing) or chemical means. (page 1 last sentence – page 2 line 6). Wu et al. teach the composition can be administered in **liquid form** with **liquid carrier**, such as **water**. (page 29, lines 10-30, particularly, lines 26-27).

Wu et al. do not teach the **actual illustration** comprising brushing tetracycline (doxycycline) composition in order to reduce plaque formation/tooth decay in a mammal.

It would have been obvious to one of ordinary skill in the art to employ the composition comprising tetracycline/doxycycline taught by Wu et al. for reducing plaque formation and tooth decay in a mammal by brushing because Wu et al. teach that the composition comprising tetracycline/doxycycline is useful for reducing dental plaque and dental caries and mechanical means of brushing is also effective in reducing dental plaque/caries. One would have been motivated to brush the teeth with Wu et al's

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composition in order to achieve an expected additive benefit both chemical means comprising tetracycline and mechanical means with brushing.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim
Art Unit 1617

Jmk
October 25, 2006